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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/220,398	12/24/98	HARNEY	P VOV-003.02

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EXAMINER

RILEY, J

ART UNIT	PAPER NUMBER
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1655

DATE MAILED:

01/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/220,398

Applicant(s)
Harney

Examiner
Jezia Riley

Group Art Unit
1655



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-42 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-42 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION**Claim Rejections - 35 USC § 112**

1. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-38, and 42 are rejected under 35 U.S.C. § 112, 2nd paragraph.

Claims 1-30 and 42 are vague and indefinite because it is unclear of what is the nature of the interaction between the nucleic acid components and the "separate nucleic acid components". Is it, for example, the relative orientations of the two components, the specific portions of the two components that interact, or the relative numbers of nucleic acid components and separate nucleic acid components that interact?

Claim 4 is vague and indefinite because it is unclear if the flanking single stranded sequences are the same "single stranded 5' or 3' terminal sequence" as recited in the base claim.

Claim 1 and 11 are vague and indefinite because it is unclear if the "nucleic acids components", "separate nucleic acid components", and "adaptor molecules" can be the same molecule or must be distinct molecules. These components are all described using identical features, 5' or 3' terminal single stranded sequences which anneal to other sequences.

Claims 17, 21, and 23 are vague and indefinite because it is unclear of what are the modifications.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-17, 25-33, and 36-38 are rejected under 35 U.S.C. § 102(b) as being anticipated by Watson et al. (1992 "Recombinant DNA, Second Ed. pp. 206-209).

Watson et al. teach nucleic acid components, separate components and adaptor molecules having 3' and 5' single stranded sequences which are annealed and ligated together. See page 207, figure 11-14, where the nucleic acids sequences are mixed together, heated, and then cooled to room temperature. During this period the sequences anneal through complementary base pairs. The sequences are designed so that each one anneals to two adjacent oligonucleotides from the opposite strand, bridging them. The annealed oligonucleotides are covalently linked by DNA ligase, producing two contiguous DNA strands. This synthetic gene is usually purified from a gel before ligation into a vector.

Claim Rejections - 35 USC § 103 (a)

5. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

6. Claims 1-42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Watson et al. (1992 "Recombinant DNA, Second Ed. Pp. 206-209) in view of Goodchild (Bioconjugate Chemistry, Vol. 1, pp. 165-187, May/June 1990, and Applicant's admissions and in further view of the 1988 Stratagene Catalog.

Watson et al. teach nucleic acid components, separate components and adaptor molecules having 3' and 5' single stranded sequences which are annealed and ligated together. See page 207, figure 11-14, where the nucleic acids sequences are mixed together, heated, and then cooled to room temperature. During this period the sequences anneal through complementary base pairs. The sequences are designed so that each one anneals to two adjacent oligonucleotides from the opposite strand, bridging them. The

annealed oligonucleotides are covalently linked by DNA ligase, producing two contiguous DNA strands. This synthetic gene is usually purified from a gel before ligation into a vector.

Goodchild teaches covalently modified nucleic acids using biotinylation, fluorescent tagging and conjugation of enzymes page 173, Table VI.

Applicant admits that modifications to form products such as PNA and yeast artificial chromosomes "can be performed by a variety of art known techniques" See, for example page 27.

Stratagene shows gene characterization kits providing a variety of different reagents. Each kit provides a variety of different reagents which have been assembled and premixed specifically for a defined set of experiments.

Thus, it would have been obvious to someone of ordinary skill in the art, at the time the invention was made to use the modified nucleic acids of Goodchild in the production methods of Watson for the expected benefit of constructing the products "used extensively in molecular biology" as explicitly taught in Goodchild, page 165, 3rd paragraph. Further, it would have been obvious to someone of ordinary skill in the art, at the time the invention was made to prepare a kit comprising derivatives such as probes materials. One would have been motivated to perform this kit as suggested by Stratagene, because it saves money and resources by reducing waste reagents since each of these reagents is needed in only microgram amounts when beginning a series of experiments, thus reducing the

accumulation of unused chemicals (see lines 12-27 Stratagene catalog p.39).

7. No claim is allowed.

Conclusion

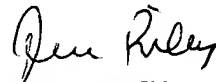
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is (703) 305-6855. The Examiner may normally be reached Monday through Friday, 0900 - 1700 EST. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Gary Jones, may be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Any necessary fax can be sent to (703) 308-4242.

jr

Wednesday, 29 December 1999


JEZIA RILEY
PATENT EXAMINER